



ATTORNEY'S DOCKET NUMBER: 2004367-0111

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Knaack *et al.*
Serial No: 10/589,226
Filing Date: January 27, 2005
Title: Stabilized Bone Graft

Examiner: Not yet assigned
Art Unit: Not yet assigned

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

1. Statement under 37 C.F.R. §§ 1.56, 1.97, and 1.98 (6 pages);
2. Form PTO-1449 (4 pages);
3. Cited art (26 references); and
4. Return Postcard.

Respectfully submitted,

C. Hunter Baker, M.D., Ph.D.
Registration No. 46,533

Choate, Hall & Stewart, LLP
Two International Place
Boston, MA 02110
t (617) 248-5215
f (617) 248-4000
cbaker@choate.com

Dated: November 30, 2006

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 30, 2006

Date

Signature

Nicole A. Dozier

Typed or Printed Name of person signing certificate



ATTORNEY'S DOCKET NUMBER: 2004367-0111

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Knaack *et al.*
Serial No: 10/589,226
Filing Date: January 27, 2005
Title: Stabilized Bone Graft

Examiner: Not yet assigned
Art Unit: Not yet assigned

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ [X] An *original* Information Disclosure Statement; or
- ☐ [] A *supplemental* Information Disclosure Statement.

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop: Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 30, 2006
Date

Nicole A. Dozier
Signature

Nicole A. Dozier
Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- ☒ Before the mailing of a first Office action on the merits; or
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby certifies that *either*:
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included, except for U.S. patents and published U.S. patent applications for which the submission requirements has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☒ A copy of each of the references cited on the attached form PTO-1449 (modified) is enclosed, except for U.S. patents and published U.S. patent applications for which the submission requirement has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☒ Does contain non-English language citations

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

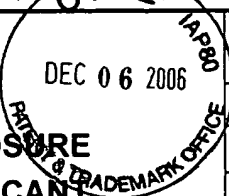
Respectfully submitted,

Dated: November 30, 2006

A handwritten signature in black ink, appearing to read 'C. Hunter Baker', is written over a horizontal line.

C. Hunter Baker, M.D., Ph.D.
Registration No. 46,533

Choate, Hall & Stewart, LLP
Two International Place
Boston, Massachusetts 02110
t (617) 248-5215
f (617) 248-4000
cbaker@choate.com

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)					
Sheet	1	Of	4	Application Number	10/589,226
				Filing Date	January 27, 2005
				First Named Inventor	Knaack <i>et al.</i>
				Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
				Attorney Docket Number	2004367-0111

U.S. PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-4,394,370	June 19, 1983	Jefferies	
		US-4,440,750	April 3, 1984	Glowacki, et al.	
		US-4,485,097	November 27, 1984	Bell	
		US-4,678,470	July 7, 1987	Nashef, et al.	
		US4,743,259	May 10, 1988	Bolander, et al.	
		US-5,236,456	August 17, 1993	O'Leary, et al.	
		US-5,284,655	February 8, 1994	Bogdansky, et al.	
		US-5,314,476	May 24, 1994	Prewett, et al.	
		US-5,490,962	February 13, 1996	Cima, et al.	
		US-5,507,813	April 16, 1996	Dowd, et al.	
		US-5,518,680	May 21, 1996	Cima, et al.	
		US-5,607,269	March 4, 1997	Dowd, et al.	
		US-5,807,437	September 15, 1998	Sachs, et al.	
		US-5,899,939	May 4, 1999	Boyce, et al.	
		US-6,294,187	September 25, 2001	Boyce, et al.	
		US-6,326,018	December 4, 2001	Gertzman, et al.	
		US-6,468,543	October 22, 2002	Gilbertson, et al.	
		US-6,696,073	February 24, 2004	Boyce, et al.	
		US-2001/0043258	November 22, 2001	Ohki	
		US-2003/0039676	February 27, 2003	Boyce, et al.	
		US-2004/0024457	February 5, 2004	Boyce, et al.	
		US-2004/0146543	July 29, 2004	Shimp, et al.	
		US-2005/0008620	January 13, 2005	Shimp, et al.	
		US-2005/0008672	January 13, 2005	Winterbottom, et al.	
		US-2005/0027033	February 3, 2005	Knaack, et al.	
		US-2005/0283255	December 22, 2005	Geremakis, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		DE- 2 253 086	October 25, 1972	Wenzel		
		EP-0 332 826	September 20, 1989	Teva Pharm Industries.		
		JP 01/179,689 (Abstract Only)	July 17, 1989	Res Dev Corp of Japan		
		WO-94/21298	September 29, 1994	Institut Pasteur		
		WO-2005/072656	August 11, 2005	Osteotech, Inc.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent

document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

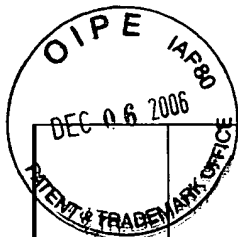
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known		
		Application Number	10/589,226	
		Filing Date	January 27, 2005	
		First Named Inventor	Knaack <i>et al.</i>	
		Art Unit	Not yet assigned	
		Examiner Name	Not yet assigned	
Sheet	3	4	Attorney Docket Number	2004367-0111

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Crowe <i>et al.</i> , "Inhibition of Enzymic Digestion of Amylose by Free Fatty Acids In Vitro Contributes to Resistant Starch Formation", <i>J. Nutr.</i> , 130 (8): 2006-8, 2000.	
		Driessens <i>et al.</i> , "Calcium phosphate bone cements", <i>Universitat Politecnica de Catalunya, Barcelona, Spain</i> , 31 : 855-77.	
		Edwards <i>et al.</i> , "Osteoinduction of Human Demineralized Bone: Characterization in a Rat Model", <i>Clinical Orthopaedics & Rel. Res.</i> , 357 : 219-228, 1998.	
		Glowacki <i>et al.</i> , "Demineralized Bone Implants", <i>Clinics in Plastic Surgery</i> , 12 (2): 233-41, 1985.	
		Han <i>et al.</i> , "Quantitative and sensitive in vitro assay for osteoinductive activity of demineralized bone matrix", <i>J. Orthop. Res.</i> , 21 (4):648-54, 2003.	
		Jain <i>et al.</i> , "Anchoring of phospholipase A2: the effect of anions and deuterated water, and the role of N-terminus region", <i>Biochem. et Biophys. Acta</i> , 860 : 448-61, 1986.	
		Katz, "The biology of heavy water", <i>Scientific American</i> , 106-116, 1960.	
		Mulliken <i>et al.</i> , "Fate of Mineralized and Demineralized Osseous Implants in Cranial Defects.", <i>Calcif. Tissue Int.</i> , 33 : 71-6, 1981.	
		Neigel <i>et al.</i> , "Use of Demineralized Bone Implants in Orbital and Craniofacial Reconstruction and a Review of the Literature", <i>Ophthal. Plast. Reconstr. Surg.</i> , 12 (2): 108-20, 1996.	
		Ray <i>et al.</i> , "Bone implants", <i>J. Bone & Joint Surgery</i> , 39-A (5):1119-28, 1957.	



		Russell <i>et al.</i> , "Clinical Utility of Demineralized Bone Matrix for Osseous Defects, Arthrodesis, and Reconstruction: Impact of Processing Techniques and Study Methodology", <i>Orthopaedics</i> , 22 (5): 524-31, 1999.	
		Ueland <i>et al.</i> , "Increased cortical bone content of insulin-like growth factors in acromegalic patients", <i>J. Clin. Endocrinol. & Metab.</i> , 84 (1): 123-7, 1999.	
		Urist, "Bone: formation by autoinduction", <i>Science</i> , 150 : 893-99, 1965.	
		Urist <i>et al.</i> , "Observations Implicating an Extracellular Enzymic Mechanism of Control of Bone Morphogenesis", <i>J. Histochem. & Cytochem.</i> , 22 (2): 88-103, 1974.	
		Urist <i>et al.</i> , "Preservation and biodegradation of the morphogenetic property of bone matrix." <i>J. Theor. Biol.</i> , 38 : 155-67, 1973.	
		Whiteman <i>et al.</i> , "Demineralized Bone Powder: Clinical applications for bone defects of the hand", <i>J. Hand. Surg (British and European Volume)</i> , 18B : 487-90, 1993.	
		Whittaker, et al, "Matrix Metalloproteinases and their Inhibitors-Current Status and Future Challenges", <i>Celltransmissions</i> , 17 (1): 3-14.	
		Xiaobo <i>et al.</i> , "Experimental and Clinical Investigations of Human Insoluble Bone Matrix Gelatin", <i>Clin. Orthop. & Rel. Res.</i> , 293 : 360-5, 1993.	
		Zhang <i>et al.</i> , "A Quantitative Assessment of Osteoinductivity of Human Demineralized Bone Matrix", <i>J. Periodontol.</i> , 68 (11): 1076-84, 1997.	
		International Searching Authority, "International Search Report," PCT Application No. PCT/US05/003092, mailed on June 23, 2005, 3 pgs.	
		International Searching Authority, "Written Opinion," PCT Application No. PCT/US05/003092, mailed on June 23, 2005, 3 pgs.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 2313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.